IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") for its Complaint against Defendants Apotex Inc. and Apotex Corp. alleges as follows:

I. THE PARTIES

1. Plaintiff Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including HETLIOZ® (tasimelteon oral capsules), for the treatment of Non-24-Hour Sleep-Wake Disorder ("Non-24").

2. On information and belief, Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

5. On information and belief, Apotex Corp. is a generic pharmaceutical company that distributes and sells generic pharmaceutical products in the State of Delaware and throughout the United States that are manufactured by Apotex Inc. (Apotex Inc. and Apotex Corp. are collectively referred to herein as "Apotex" unless otherwise specified).

II. NATURE OF THE ACTION

6. This is an action arising under the patent laws of the United States (Title 35, U.S. Code, §§ 100, *et seq.*) based upon Apotex's infringement of one or more claims of Vanda's U.S. Patent No. 10,149,829 ("the '829 patent"), which, in relevant part, generally relates to the use of tasimelteon in the treatment of Non-24.

7. Vanda is the holder of approved New Drug Application No. 205,677 for Hetlioz® (tasimelteon) capsules, 20 mg, which was approved by the Food and Drug Administration ("FDA") on January 31, 2014, for the treatment of Non-24 ("HETLIOZ® NDA").

8. Tasimelteon is the active ingredient in HETLIOZ®.

9. On information and belief, Apotex filed Abbreviated New Drug Application No. 211607 (the "ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 ("Apotex's ANDA Product").

10. On information and belief, Apotex made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the '829 patent is invalid, unenforceable, and/or that certain claims will not be infringed by Apotex's ANDA Product.

11. Vanda received written notice of Apotex's ANDA and Paragraph IV Certification as to the '829 patent on February 28, 2019 ("Notice Letter"), along with an enclosed statement of Apotex's alleged factual and legal bases for stating that the '829 patent is invalid, unenforceable, and/or will not be infringed by Apotex's ANDA Product ("Detailed Statement").

12. Apotex's Detailed Statement does not provide any factual bases for stating that the '829 patent is unenforceable.

13. This action is being commenced within 45 days of receipt of Apotex's Notice Letter.

14. Apotex has infringed one or more claims of the '829 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Apotex ANDA with a Paragraph IV Certification and seeking FDA approval of the Apotex ANDA prior to the expiration of the '829 patent or any extensions thereof.

15. Apotex has infringed one or more claims of the '829 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Apotex ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic tasimelteon for the treatment of Non-24 prior to the expiration of the '829 patent or any extensions thereof.

III. JURISDICTION

16. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Apotex Corp. because Apotex Corp. is incorporated in the State of Delaware.

18. On information and belief, Apotex Corp.'s registered agent for service of process is Corporate Creations Network, Inc., with an address at 3411 Silverside Road #104, Tatnall Building, Wilmington, Delaware 19810.

19. This Court has personal jurisdiction over Apotex Inc. under Fed. R. Civ. P. 4(k) because, on information and belief, Apotex Inc. is organized under the laws of Canada.

20. This Court has personal jurisdiction over Apotex Inc. because at least one of the provisions under Del. Code Ann. tit. 10, § 3104, is satisfied. On information and belief, Apotex satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), and § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State").

21. This Court also has personal jurisdiction over Apotex Inc. because this suit arises out of and relates to Apotex Inc.'s activities, in concert with Apotex Corp., that are, and will be, directed to Delaware. On information and belief, following any FDA approval of the Apotex ANDA, Apotex Inc., in concert with Apotex Corp., will market and sell Apotex's ANDA Product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States, including this judicial District.

22. On information and belief, Apotex Inc., directly and through its subsidiaries, affiliates, or agents, including Apotex Corp., is in the business of manufacturing

generic pharmaceuticals that it distributes or has distributed in the State of Delaware and throughout the United States.

23. Apotex Inc. and Apotex Corp., acting in concert, have committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Vanda, which manufactures HETLIOZ® for sale and use throughout the United States, including in this judicial District. On information and belief, and as indicated by the Notice Letter, Apotex prepared and filed ANDA No. 211607 with the intention of seeking to market generic tasimelteon nationwide, including within this judicial District.

24. On information and belief, Apotex plans to market and sell generic tasimelteon in the State of Delaware, list generic tasimelteon on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursement for sales of the ANDA products in the State of Delaware, either directly or through one or more of Apotex's wholly owned subsidiaries, agents, and/or alter egos.

25. On information and belief, Apotex knows and intends that its proposed generic tasimelteon product will be distributed and sold in Delaware and will thereby displace sales of HETLIOZ®, causing injury to Vanda. Apotex intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic tasimelteon product.

IV. VENUE

26. Venue is proper in this judicial District under 28 U.S.C. § 1391(b) and (c) and § 1400(b) because Apotex Corp. is incorporated in the State of Delaware and Apotex Inc. is incorporated in Canada and may be sued in any judicial district in the United States in which Apotex Inc. is subject to the court's personal jurisdiction.

V. THE PATENT-IN-SUIT

(U.S. PATENT NO. 10,149,829)

27. The allegations above are incorporated herein by reference.

28. The '829 patent covers the use of tasimelteon to treat patients with Non-24.

29. As explained in the '829 patent, "Non-24 occurs when individuals, primarily blind with no light perception, are unable to synchronize their endogenous circadian pacemaker to the 24-hour light/dark cycle. Without light as a synchronizer, and because the period of the internal clock is typically a little longer than 24 hours, individuals with Non-24 experience their circadian drive to initiate sleep drifting later and later each day. Individuals with Non-24 have abnormal night sleep patterns, accompanied by difficulty staying awake during the day." As also explained in the '829 patent, "[t]he ultimate treatment goal for individuals with Non-24 is to entrain or synchronize their circadian rhythms into an appropriate phase relationship with the 24-hour day so that they will have increased sleepiness during the night and increased wakefulness during the daytime."

30. The '829 patent explains that "[t]asimelteon is a circadian regulator which binds specifically to two high affinity melatonin receptors, Mel1a (MT1R) and Mel1b (MT2R). These receptors are found in high density in the suprachiasmatic nucleus of the brain (SCN), which is responsible for synchronizing our sleep/wake cycle."

31. Vanda is the owner of all rights, title, and interest in the '829 patent, entitled "Treatment of Circadian Rhythm Disorders." The USPTO duly and legally issued the '829 patent on December 11, 2018, to Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '829 patent is attached to this Complaint as Exhibit A.

32. The ’829 patent generally claims methods of treating Non-24 by avoiding the use of tasimelteon in combination with a CYP1A2 inhibitor, such as fluvoxamine. As an example, claim 1 of the ’829 patent claims “[a] method of treating a patient for a circadian rhythm disorder or for a sleep disorder wherein the patient is being treated with a strong CYP1A2 inhibitor selected from a group consisting of fluvoxamine, ciprofloxacin, and verapamil, the method comprising: (A) reducing the dose of the strong CYP1A2 inhibitor treatment and then (B) treating the patient with tasimelteon, wherein the exposure to tasimelteon in a patient being treated with tasimelteon for a circadian rhythm disorder or for a sleep disorder is reduced.”

VI. COUNT I

(INFRINGEMENT OF THE ’829 PATENT)

33. The allegations above are incorporated herein by reference.

34. Apotex filed the Apotex ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the ’829 patent and any extensions thereof.

35. Apotex’s Notice Letter states that Apotex filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the ’829 patent. The Notice Letter represents that an Amendment to Apotex’s ANDA was submitted with a Paragraph IV Certification that the ’829 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex’s ANDA Product.

36. Apotex thus has actual knowledge of the ’829 patent.

37. The FDA-approved HETLIOZ® Label instructs physicians that “HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).”

38. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

39. The HETLIOZ® Label further instructs physicians to "[a]void use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions."

40. On information and belief, the Apotex ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

41. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '829 patent, and Vanda has the right to enforce the '829 patent and sue for infringement thereof.

42. The '829 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for HETLIOZ® in its 20 mg strength.

43. On information and belief, the Apotex ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe claims 1–14 of the '829 patent.

44. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claim 1–14 of the '829 patent.

45. Apotex has infringed the '829 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength for the treatment of Non-24, which is covered by one or more claims of the '829 patent, prior to the expiration of the '829 patent.

46. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '829 patent, including claim 1–14 under 35 U.S.C. § 271(a), (b), and/or (c).

47. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

48. Vanda seeks entry of an order declaring that Apotex has infringed the '829 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

49. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the '829 patent or any later expiration of exclusivity for the '829 patent to which Vanda becomes entitled.

50. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '829 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

51. On information and belief, Apotex's statement of the factual and legal bases for its opinion regarding the invalidity and noninfringement of the '829 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

52. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Apotex and grant the following relief:

A. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the '829 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '829 patent;

B. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the '829 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '829 patent;

C. an order requiring that Apotex amend its Paragraph IV Certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

D. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '829 patent or any later period of exclusivity to which Vanda is or may become entitled;

E. a permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '829 patent, or contributing to or inducing

anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

F. an order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '829 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

G. an assessment of pre-judgment and post-judgment interest and costs against Apotex, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

H. an award to Vanda of its attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

I. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs

Karen Jacobs (#2881)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
kjacobs@mnat.com
dfahnestock@mnat.com

Attorneys for Plaintiff
Vanda Pharmaceuticals Inc.

OF COUNSEL:

Nicholas Groombridge
Eric Alan Stone
Kira A. Davis
Josephine Young
Daniel J. Klein
Jennifer Rea Deneault
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

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